APRIL 1, 2010
The Most Frequently Asked Questions of the Bureau

M2000 Drug Regimen Review

1) Q: Is it correct that Physical Therapists now have it in their scope of practice to do the Drug Regimen Review?

   A: **NO**. A Physical Therapist cannot do the complete drug regimen review as outlined in the Conditions of Participation CFR 484.55(c). The Bureau has recently contacted the State Board for Physical Therapists and received confirmation that drug regimen review is NOT part of the physical therapist scope of practice. Therefore, the complete drug regimen review, in a therapy-only case, must still be performed by the registered nurse.

   I think some of the confusion has been the result of misinterpretation of the information on the OASIS-C; specifically in regards to whether it is still expected that a therapist should be able to do the OASIS-C with all the new data items that have been added. CMS has made it clear that the Conditions of Participation have not changed. In a therapy-only case, the therapist can do the OASIS-C assessment; however, there has to be documentation in the medical record that the drug regimen review was performed by the registered nurse. The physical therapist will then answer M2000 and the M0090 date would be the date that the therapist and the registered nurse collaborated.

   Further confusion stemmed from CMS's trainings on OASIS-C in which a slide that is titled "What about PTs?" In this slide they shared the comments from the American Physical Therapy Association regarding whether PTs can respond to the new items in OASIS-C. It states, "It is within the scope of the PTs to perform a patient *screen* in which medication issues are assessed, even if the PT does not perform the specific care needed to address the medication issue." This does not say that it is within the scope of practice of the therapist to conduct a *complete* drug regimen review.

   Questions #32 and #32.1, Category 2-Comprehensive Assessment, from the CMS Q&As somewhat address this issue.

2) Q: An agency writes, "We have several physicians that are complaining about us sending them information or contacting them when we have patients that have clinically significant medication issues. We have had some come to the point of saying they would quit referring to us if we did not stop sending them all of this information. What can we do?"

   A: M2000 defines in the Response-Specific Instructions what CMS feels are “Potential Clinically Significant Medication Issues”. Therefore, I am finding that agencies are answering “2” if ***any*** of those issues are present and are contacting the physician for reconciliation by sending them lots of medication information.

I've looked in the published CMS Q&As that are available so far (Oct 2009 and Jan 2010) to see if there was any further guidance on this M item that could help clarify this item and have found none that specifically address this. ***Question # 33 in the October Quarterly Q&As*** somewhat touches on the issue of what is considered "clinically significant".

However, I had sent a similar question to CMS and I will quote to you their response. (I'm hoping this will be addressed in the April 2010 set of Q&As so it will be available to all agencies.)

In the question I sent to CMS, I pointed out to them what their definition of "Potentially Clinically Significant Medication Issues" is in Chapter 3 and how those issues are found in a lot of patients.

Per e-mail response from CMS:
"Clinically significant medication issues are those that, in the care provider's clinical judgment, pose an actual or potential threat to patient health and safety. The "potential" clinically significant medication issues included in the M2000 Response-Specific Instructions require the clinician's judgment to determine whether or not they are truly clinically significant problems that must be reported to the physician. "

Based on CMS's response to my question, this is how I would recommend agencies approach their response to M2000. If the clinician assessing the patient's medications find something with the medications as outlined in the Response-Specific Instructions for M2000, then they need to determine, **based on their clinical judgment**, whether or not they feel it is truly clinically significant or not. If it is in their clinical judgment that they do not feel the issue is truly **clinically significant**, than the answer to M2000 would be "1 - No problems found during review" and therefore, M2002 would be skipped.

As clinicians, you have to make decisions every day as to whether you feel something is clinically significant and needs reporting to the physician. Based on your decision, you then take responsibility for that decision. If it is clinically significant, the physician should feel it was appropriate to make the contact.

3) An agency writes, "On discharge from the hospital, the discharging physician or the pharmacist does a full drug regimen review on all the discharge meds for the patients. Can the agency use this review as the complete drug regimen review for their patients as long as they have the documentation of the review in the chart? The documentation would include who is doing the review and the person's title."

A: ***Per e-mail response from CMS***: "M2000 is specifically asking if the drug regimen review indicates potential clinically significant issues. The drug regimen review must be completed by the home health agency, per the Conditions of Participation 484.55. This is unchanged by the additional role the OASIS-C has in gathering information regarding this standard. "

M2002 Medication Follow-up

1) Q: "We are having difficulty getting the physician's to review the medications and get back to us within 24hrs. What can we do to be in compliance?"

   A: First, the physician is not the one to review the medications; the registered nurse is to do the medication review. As stated in the Conditions of Participation 484.55(c), "The comprehensive assessment must include a review of all medication the patient is currently using in order to identify any potential adverse effects….". Per 484.55(b)(2), "Except as provided in paragraph (b) (3) of this section, a registered nurse must complete the comprehensive assessment……". 484.55(b)(3) states "When physical therapy, speech-language pathology, or occupational therapy is the only service ordered by the physician, a physical therapist, speech-language pathologist or occupational therapist may complete the comprehensive assessment …".
   Because, in the state of Missouri, a complete medication review is not in the scope of practice for therapists, the registered nurse must do the complete medication review as outlined in the Conditions of Participation.

   Secondly, the "one calendar day" response time is only if the physician was notified of a potentially clinically significant medication issue.

   At this time, there is no CMS Q&A that specifically addresses this issue.

2) "If an agency phones the physician on-call (it's a weekend) and he responds but because he doesn't really know the patient has asked the agency to just contact the primary care physician on Monday, can the clinician mark #1 Yes?"

   A: ***CMS has reconsidered the answer they originally gave on this question. The final answer was published in the January 2010 Quarterly Q&As, Question #16.*** It states, "When completing M2002, Medication Follow-up, if the physician or physician designee responds within one calendar day and there is a resolution to the clinically significant medication issue or a plan to resolve the issue, Response "1-Yes" should be selected. In your scenario, you describe a situation where the physician was contacted and informed of the medication issue, but due to the contacted physician's unfamiliarity with the patient; you were directed to contact the primary care practitioner on Monday. Therefore, no one reconciled, or formulated a plan to reconcile the specific medication issue identified within one calendar say, so "0-No" should be selected.

3) An agency writes, "I am aware that in order to mark response "1", the two-way communication AND reconciliation must be completed by the end of the next calendar day after the problem was identified. Does that "next calendar day" have to be within the 5 days for SOC and 48 hrs for ROC? That is, if the nurse finds a problem with the patient's meds on day 5 of the SOC and the physician is notified and the problems are reconciled but not until day 6 (although it is within the one calendar day) can "1" be marked?"

   A: ***This answer can be found in the October 2009 Quarterly Q&As, Question # 34 and Question # 17 in the January 2010 Quarterly Q&As*****:** "In order to select response 1, the two-way communication AND reconciliation (or plan to resolve the problem) must be

completed by the end of the next calendar day after the problem was identified. " "M2002, Medication Follow-up, is only collected at the SOC and ROC. The item must be answered within the timeframe allowed at the SOC/ROC to ensure compliance with the Condition of Participation regarding the completion of the comprehensive assessment. If a problem is identified, the communication and reconciliation (or plan to resolve the problem) must occur within one calendar day of identification and before the end of the allowed timeframe in order to answer "1-Yes". If a medication issue is identified on day 5 after the SOC, the physician is contacted within one calendar day and response back with a plan for reconciliation on day 6 after the SOC, this 2-way communication could not be captured at the SOC, but M2002 could be marked "1-Yes" at the ROC time point, reflecting that the identification and 2-way communication w/plan for reconciliation had occurred as required by the item. "

M2010 Patient/Caregiver High Risk Drug Education
M2015 Patient/Caregiver Education Intervention

1) An agency asks, "We know pharmacies are releasing drug education sheets to patients when they dispense their meds. M2015 states, "Since the previous OASIS assessment, was the patient/caregiver instructed by agency staff or other health care provider…The question is, is the pharmacy's drug education sheets considered "other health care provider" in this item?"

   A: ***Per e-mail response from CMS***: "If assessment of the patient/caregiver's baseline knowledge reveals the patient received the education specified in M2015, Patient/Caregiver Drug Education Intervention, from the pharmacist, you can include this education in M2015. This would require the pharmacist educated the patient/caregiver to monitor the effectiveness of all drug therapy (prescribed, as well as all OTC), drug reactions, and side effects, and how and when to report problems that may occur to the appropriate care provider. Note that just including written materials in the bag with the medications at the time the medication is dispensed may not provide the specific education. The education of the patient may also be a collaborative effort, in which the pharmacist may provide part of the education, with other healthcare providers.

   A Q&A published in the January 2010 Quarterly Q&As, Question # 20, somewhat addresses this same situation.

2) In a multidisciplinary case, can a nurse, other than the nurse seeing the patient in the home, do the drug regimen review (M2000) or the patient education (M2010)(2015)? Can a nurse from the office give the patient education over the phone?

   A**: Per e-mail response from CMS**: "An RN in the office could work collaboratively with the visiting nurse and provide drug education over the phone as long as the nurse determines through assessment and evaluation that the educational intervention was appropriate based on the needs of the patient. The educational intervention must be appropriately documented and communicated back to the RN responsible for completing M2000/M2010/M2015 as part of the comprehensive assessment.

There is no CMS Q&A specifically addressing this issue at this time.

M2250 Plan of Care Synopsis
M2400 Intervention Synopsis

1) I have received numerous questions regarding this item. Most of them revolve around the same issue; that is, how do you get the orders from the physician in the required time frame; how specific do the orders have to be, and do the orders have to be signed. Some agencies are also confusing this item with M2002 in regards to the time requirement, thinking they have to get all this done in one calendar day.

   A: There are several CMS Quarterly Q&As that have already been published regarding this OASIS item in both the October 2009 and January 2010 Quarterly Q&As. However, only a couple of the Q&As somewhat address the issues mentioned above.

   January 2010, Question #24 states, "It is understood that some of the best practices captured in M2250 includes care that might be routinely provided to a patient without a specific order. For instance, you may be admitting a patient for wound care, and in the process of your assessment, encounter a fall risk, like clutter on the floor. You might resolve the issue through intervention or education, all without obtaining a physician's order. However, if your agency wants to "get credit" for conducting this fall prevention intervention (by marking "yes" on M2250(c)), you must have an order for fall prevention interventions."

   January 2010, Question #25 states, "The OASIS-C process measure are not changing the expectations and requirements for communicating with the physician to obtain verbal orders prior to providing services. The Medicare Benefit Policy Manual defines clearly how orders can be obtained verbally if complete orders were not provided in the referral. Chapter 7, Section 30.2.5 states: "Services which are provided from the beginning of the 60-day episode certification period based on a request for anticipated payment and before the physician signs the plan of care are considered to be provided under a plan of care established and approved by the physician where there is an oral order for the care prior to rendering the services which is documented in the medical record and where the services are included in a signed plan of care." All orders would be under the same instruction from CMS, including those which are reported in M2250 and M2400."

   The Bureau/surveyors have discussed the above guidance from CMS. Many of you have asked if the orders outlined on the Home Health Certification and Plan of Care (CMS 485) would meet the requirements as outlined in M2250, Plan of Care Synopsis. The Home Health Certification and Plan of Care (CMS 485) is a verbal order. Per Medicare A Newsline, December 1, 1999, Vol. 7, No. 3, "…Locator 23 of the HCFA-485 is used to document the date the qualified personnel spoke to the attending physician and received the verbal authorization to see the patient and received the order for care. This locator requires the dated signature (not initials) of the person who actually received the verbal order from the physician….".

Therefore, it is the interpretation of the Bureau, if the specific orders as outlined in M2250 are on the CMS 485 and is signed by the clinician who took the orders from the physician (verbal order), then this would meet the intent of the item.

As far as the time requirements for obtaining (not signed) orders as outlined in M2250, ***Chapter 3 of the OASIS Guidance Manual, the Response-Specific Instructions for M2250*** states, "These Plan of Care orders must be in place within the 5-day SOC window and the 2-day ROC window in order to meet the measure definition." **There is no one-calendar day requirement for this item.**

2) If we phone the physician and ask if he/she wants to give patient specific parameters and he says "no" and we ask if we can use our own agency's parameters which are….and the physician agrees with these parameters, would M2250 be marked "Yes"?

A: ***Per e-mail response from CMS***: " When completing M2250 (a), Patient –Specific parameters, at the SOC or ROC, the clinician will answer:
"Yes" if the plan of care includes specific parameters ordered by the physician for this specific patient ***or after reviewing the agency's standardized parameters with the physician; he/she agrees they would meet the needs of this specific patient.***
"No" if there are no patient specific parameters on the plan of care and the agency will not use standardized physician notification parameters for this patient.
"NA" if the physician has chosen not to establish patient-specific parameters and the agency uses their own agency standardized guidelines. "

This question is also addressed in the January 2010 CMS Quarterly Q&As, Question # 28.

3) If the clinician did not do one of the ***standardized*** assessments (falls risk, depression, pain, etc.) but their clinical assessment does indicate the patient is not at risk for falls, or the patient did not require further intervention for depression, or was not in pain, can they mark "NA"?

A: ***Per e-mail from CMS:*** "For M2250, it is not required that the "formal" assessment as specified in the item be completed, just that "an" assessment revealed no pain, no risk for pressure ulcers, no risk for falls. M2400, Intervention Synopsis, however, does require the "formal" assessment as referenced in M1240, M1300, M1730 and M1910 must have been conducted in order to select "NA".

There is no CMS Q&A that directly addresses this issue for M2250; however, January 2010, Quarterly Q&As, Question # 29 does address this issue when responding to M2400.

4) Does the inclusion of existing ordered antidepressant medication on the medication profile equate to a "Yes" response to Depression Interventions on M2250 and/or M2400?

A: ***Per CMS January 2010 Quarterly Q&As, Question # 26:*** M2250, Plan of Care Synopsis and M2400 Intervention Synopsis, report whether the physician ordered plan

of care includes depression interventions. The presence of an existing antidepressant medication in the medication profile/plan of care is considered a depression intervention.

5) For M2250 and M2400, if I have specific orders in the plan of care for the best practices as outlined in the item and implemented them during the episode of care, can I mark "yes, even though I may not have done a formal assessment during the required time frame? For example, I did not complete a formal falls risk assessment with 5 days of the SOC; however, I do have orders from the physician for falls prevention measures.

   A: ***Per CMS October 2009 Quarterly Q&As, Question # 41***: " Yes, M2250 reports if the physician-ordered plan of care includes specific interventions and should be marked "No" or "Yes", depending on the presence of the orders, whether or not a formal assessment for the related issue was conducted. M2400 reports if specific interventions were BOTH included in the physician-ordered plan of care AND implemented. M2400 should also be marked "No" or "Yes" based on the presence of the orders and documentation of their implementation, whether or not a formal assessment for the related issues was conducted. If no orders were present, "NA' maybe appropriate to mark, if the situation meets the conditions stated in the specific NA statements (e.g., "NA, Patient has no diagnosis or symptoms of depression).